

Advanced Research and Development Programs for Medical Innovation Application Q&A

Q&A information can also be found on the website for research proposal solicitations below. For contents that draws frequent inquiries, we intend to update the information as required.

URL: <http://www.amed.go.jp/koubo/010720170310-01.html>

Refer to the following website for the operation of the Cross-ministerial R&D Management System (e-Rad), affiliated research institutions, researcher registration and how to use e-Rad:

URL : <http://www.e-rad.go.jp/>

1. Matters related to both AMED-CREST and PRIME

(1) Consent of affiliated institutions

Q: When making an application, is the consent of the affiliated institution required?

A: Yes. Beginning with solicitations for proposals for FY2017, an institution consent process has been added for applications submitted via e-Rad, so please take note of this change. If an R&D proposal is selected for the program, a contracted R&D agreement shall be concluded between the research institution where the R&D PI conducts research and AMED. Furthermore, in the case of AMED-CREST, the subsidiary institution with which the R&D Co-Investigator is affiliated shall conclude a subcontracted R&D agreement with the principal institution to conduct R&D subcontracted from the principal institution to the subsidiary institution. When submitting an application via e-Rad, please ensure that the PI confirms that the proposal has the consent of the subsidiary institution also before obtaining the consent of the principal institution, and this should be conveyed to affiliated research institutions.

However, in the case of principal institutions and subsidiary institutions that are national facilities or institutions, etc. (a general term referring to national facilities, institutions, and public research institutes, etc.), only in the case that the R&D PI or R&D Co-Investigator affiliated with the relevant institution makes a request based on reasonable grounds shall AMED provide the R&D PI or R&D Co-Investigator affiliated with the relevant institution with R&D grants following discussions with AMED.

In the case of subcontracted R&D agreements, as a general rule the subcontracted institution shall perform institution accounting under the condition that they respond to requests by AMED to conduct audits, etc.

(2) Applying to JST Strategic Basic Research Programs

Q: Is it possible to apply simultaneously to both JST CREST/PRESTO and AMED-CREST/PRIME?

A: Possible, because of no restriction between them. However, as described in “III. 3. (2) Review Criteria and Perspectives in Evaluating Projects” in the Application Guidelines, please note that selection is performed with the viewpoint of “unreasonable duplication” and “excessive concentration” of research funds.

(3) Project of JST Strategic Basic Research Programs on going.

Q: Is it possible to apply to AMED-CREST or PRIME, although now executing JST CREST or PRESTO?

A: Possible, because restriction is not set against research areas now executed in JST. However, application is not allowed for R&D PI who was awarded in JST until FY 2014 and now executes a project in the transferred R&D areas in AMED, with exception that the project is going to finish within FY 2017.

(4) Use of color in Research Proposals

Q: Is it possible to use color for text or figures in research proposals? Do evaluators read R&D proposals in color quality when assessing research proposals?

A: Evaluators do read research proposals in color quality when assessing them. However, proposals may be printed out from PDF files, so we ask that you take care to use figures and tables that are easy to read, even at low resolutions.

(5) Submission of applications when the PI is affiliated with an overseas research institution and securing of a facility for conducting research in Japan

Q: I am currently affiliated with an overseas research institution; can I apply to the program?

A: In the case of PRIME, it is possible to submit an application on the condition that you are able to establish a system for conducting R&D at a research institution in Japan by the date that R&D is due to commence (October 1). In the case of AMED-CREST, it is possible to submit an application on the condition that you have been accepted by a research institution in Japan and have obtained the consent of the research institution to carry out the R&D project.

(6) Personnel Transfers Following the Proposal Selection

Q: If the R&D PI experiences a change of position (promotion, transfer to a different research institution, etc.) while conducting research, will the R&D PI be permitted to continue research projects?

A: Provided it is possible to continue research projects unhindered following the change of position, R&D projects may be continued. Having another person take over as R&D PI as a result of a change of position, however, is not permitted.

(7) Movement of equipment etc.

Q: If the research institution affiliation changes because of the personnel transfer, or other reason, while R&D is being conducted, is it possible to move the equipment, etc. purchased with research funds to the new research institution?

A: Equipment, etc. purchased with funds accounted for as R&D costs (direct cost) must, in principle, be moved, via transfer of ownership, etc. to the new research institution in accordance with the R&D agreement.

(8) Use of R&D Costs

Q: Is it possible to subcontract program preparation and other work to an external company, etc.?

A: If it is required to facilitate R&D work, it is possible. However, this is based on the premise that subcontracting work to outside parties is based on subcontracting agreements that exclude R&D work. In principle, R&D work may not be subcontracted.

(9) The roles of PS and PO

Q: Who is the Program Supervisor (PS) or the Program Officer (PO) for the program? What roles do they perform?

A: The Program Supervisor (PS) is a Research Supervisor and the Program Officer (PO) a Deputy Research Supervisor. The PS and PO are responsible for determining the policy of operating R&D areas, selecting R&D themes, adjusting and approving R&D projects (including R&D funds, R&D unit organization), as well as exchanging opinions with R&D PI by visiting their research facilities, providing advice and instructions on R&D projects, evaluating R&D themes and operating R&D Areas with the required means.

(10) The information about the selection in FY2016

Q: Please provide information on the research topics selected and applications submitted for the previous fiscal year.

A: The information about the selection in FY2016 is shown on the website as follows;
http://www.amed.go.jp/koubo/010720160323_kettei.html

(11) Researcher Number

Q: What is the researcher number referred to in Form 1?

A: An 8-digit researcher identification number assigned when researcher information is registered on the e-Rad system (cross-ministerial R&D Management system [<http://www.e-rad.go.jp/>]). For the registration of researcher information, refer to “II. 2. (3) Submission of Proposal Documents” in the Application Guidelines.

Q: At present, I am affiliated with an overseas research institution and have no researcher number. What should I do?

A: Personally apply for a researcher registration by sending a completed Researcher Number Issuance Request Form, a copy of ID and other required documents directly (by postal mail) to the e-Rad system administrator. For details, go to the e-Rad portal site, click on “For Researchers” and check the information provided.

(12) About interview

Q: If the date of the interview conducted as part of the selection process is inconvenient, is it possible to have someone else be interviewed in my place? Alternatively, is it possible to set a different interview date?

A: It is not possible to have someone else interviewed in your place. In addition, since interview dates were set by coordinating the schedules of numerous evaluators, setting a different interview date is also not possible. Please check the interview period information shown in “III. 2. (4) Schedule” of the Application Guidelines. Interview schedules for individual R&D Areas will be posted to the call-for-proposals website below.

(13) Life events

Q: Is it possible to suspend and later resume R&D project in response to life events (childbirth, child care and nursing care)?

A: If the R&D PI experiences a life event, it is possible, upon consultation with the PS/PO, to suspend R&D work for periods of time designated for individual life events and later resume work. In this case, the R&D project, including R&D costs, will be reviewed taking the effects of suspension on the project into consideration.

2. Matters regarding AMED-CREST

(1) Requirements for Applicants

Q: Is it possible for non-full-time researchers (guest researchers, etc.) to submit R&D proposals ? Also, is it possible for researchers scheduled to retire during the R&D period to submit proposals ?

A: Both are possible if you can establish your own R&D project organization at a domestic (i.e. Japan-based) research institution during the R&D period and it is possible for AMED to enter into a R&D agreement with the research institution. With regard to Principal Institutions and Subsidiary Institutions that are national facilities or other institutions (general term for national facilities or other institutions or public research institutes), only in the case that the relevant institution or the PI or Co-Investigator affiliated with the relevant institution makes a request based on reasonable grounds and following discussion with AMED shall a payment method of the R&D grant being paid By AMED to the PI or Co-Investigator of the relevant institution be adopted.

(2) R&D Organization and Budget Allocation

Q: Please cite R&D Co-Investigator group organizational approaches and R&D Co-Investigator group budget allocations that are unacceptable.

A: Unacceptable organizational approaches include (but are not limited to) those in which: 1) The R&D PI does not play the central role in the R&D organization for pursuing the proposed R&D initiative; 2) A substantial portion of the R&D is subcontracted to one or more external part(ies); 3) The role and position of the R&D Co-Investigator group within the R&D initiative is unclear; and 4) The budget is allocated equally to the R&D Co-Investigator group without considering its role and position.

Q: Is it possible to change the R&D project organization and total budget included in the R&D proposal when in the interview?

A: Selections are based on the contents of R&D proposals, so please be very careful to create a R&D proposal that you will not want to change later. It should be noted, though, that at the time selections are to be made, changes can be requested in accordance with instructions from the PS.

(3) R&D Cost Recording

Q: Is it necessary to include the following in the R&D proposal: 1) Bases for recording R&D costs and 2) Yearly budgets?

A: It is not necessary to include the bases for recording R&D costs, but do include the R&D budget plans by item and research group in the R&D Proposal (Form 7). In addition, those selected for participation in the interview phase of the selection process will be asked to prepare “supplementary information” covering matters such as details of R&D expenditure.

Q: After a research R&D proposal is selected, how should the R&D expenditure be allocated within the team unit?

A: When a research proposal is selected, the allocation of R&D expenditure within the team unit is determined based on the overall R&D plan and the annual R&D plan prepared every fiscal year. For more information on R&D plans, please refer to “VI. 1. Project Management” of the Application Guidelines.

(4) Research Unit Organization

Q: Is it possible for multiple organizations to form a single group? Is it necessary for groups to always be divided by a research institution?

A: A single group can consist of the members from some different institutions, if it is suitable and necessary to achieve the objective of your research. However, if the budget will be implemented by each individual institution, each institution should make a R&D agreement. For details, please inquire after your proposal has been approved.

Q: Is it possible to include a researcher affiliated with an overseas research institution in an R&D unit as the R&D Co-Investigator?

A: It is possible in the case that the required conditions are fulfilled. For example, participation of the relevant researcher is essential for realization of the proposed R&D concept; it is possible to conclude a subcontracted R&D agreement with the principal institution; and intellectual property is transferred to the principal institution. Please refer to the conditions stipulated in “II. 2. Requirements for Organizing a R&D Project” in the Application Guidelines.

Q: What criteria will be used to determine whether the implementation of research would be difficult if not done at a foreign institution?

A: The criteria for conducting research in a foreign institution are shown below.

1. Required facilities do not exist in Japan and have been installed only at a foreign institution.
2. Field studies that can be performed only overseas are required.
3. Research materials can be obtained only at a foreign research institution or foreign location and cannot be brought to Japan.

(5) Contracted R&D Agreement

Q: Is the contracted R&D agreement of the research institution to which the R&D Co-Investigator is affiliated concluded in the form of a subcontracted R&D agreement with the research institution with which the R&D PI is affiliated and not directly with AMED?

A: Yes. Under this program, beginning with awarded projects for FY2017, R&D conducted by the subsidiary institution takes the form of R&D subcontracted from the principal institution. Accordingly, AMED only concludes a contracted R&D agreement with the principal institution, and the subsidiary institution concludes a subcontracted R&D agreement with the principal institution. Even though the agreement is in the form of a subcontracted agreement, please ensure that R&D obligations are fully met. For details regarding subcontracting, please refer to the “Administration Manual for Contracted R&D Agreement in Japan Agency for Medical Research and Development” on the AMED website.

(6) R&D Evaluations

Q: How is the selected research evaluated?

A: In principle, the R&D project undergoes:

- 1) A mid-term review around three years after the start and
- 2) An ex-post evaluation at the end of the R&D period.

For more information, please refer to “VI. 2. Evaluation” of the Application Guidelines.

(7) Duplicate Applications

Q: Is it possible to make an AMED-CREST R&D proposal as the R&D PI and participate in another R&D proposal as the R&D Co-Investigator?

A: It is possible, but if both proposals are short-listed, R&D funding may be reduced or the researcher in question may be asked to participate in only one of the R&D projects, depending on factors such as the details and scale of the R&D to be performed. It should be noted that the applications by changing places the R&D PI with R&D Co-Investigator are not permitted. For more details, please refer to “II. 3. Limitations on Duplicate Applications” of the Application Guidelines.

3. Matters regarding PRIME

(1) Requirements for Applicants

Q: Does the PRIME program have an age limit?

A: There is no definitive age limit. However, it is hoped that PRIME can help to boost the careers of young researchers.

Q: Is it possible for part-time researchers (guest researchers, etc.) to submit R&D proposals?

A: The PRIME program has no restrictions in terms of the institutional affiliations or positions of applicants. Whether an applicant is a full-time employee of a research institution or not, and whether paid or not, is not considered in the selection process.

Q: Is it possible to submit a PRIME research proposal and participate as the R&D Co-Investigator in AMED-CREST R&D project?

A: It is possible to submit a PRIME R&D proposal. However, if the subject researcher has been already participating in a AMED-CREST R&D project as the R&D Co-Investigator and his/her PRIME R&D proposal is short-listed, or if both the subject researcher's PRIME R&D proposal and the AMED-CREST R&D proposal, where participating as the R&D Co-Investigator, are short-listed, adjustments, such as choosing either participation in the AMED-CREST R&D project or pursuing the PRIME R&D project, may be required (excluding projects ending in FY2017). It is advisable, therefore, to consult in detail with the person who is or would be the AMED-CREST R&D PI before submitting a PRIME R&D proposal.

Q: Can fellowship researchers at the Japan Society for the Promotion of Science apply for the PRIME program?

A: There are no restrictions on the applicant's position at the time of application. Researchers who are currently performing work under the system of an institution other than AMED, or who are going to apply to do so, should ask the relevant institution whether it is appropriate to perform work concurrently under its system and the PRIME program.

(2) R&D Cost Recording

Q: Is it necessary to include the following in the R&D proposal: 1) Bases for recording R&D costs and 2) Yearly budgets?

A: It is not necessary. However, those selected to participate in the interview phase of the selection process will be asked to prepare "supplementary information" covering matters including details of R&D budget etc.

(3) R&D participants

Q: Is it necessary to describe R&D participants in form 5 of R&D proposal?

A: If R&D participants such as a research assistant are present, please describe them in a conceivable manner at the time of application.

(4) Personnel costs

Q: Is it possible to pay personnel costs of R&D PI by R&D fund? Can personnel costs be paid separately?

A: As described in "II. 1. Eligible Applicants" in the Application Guidelines, applicants must be affiliated with a domestic Japanese research institution, and in general, they will organize a system for carrying out the proposed R&D at the institution. Therefore, in general, the personnel cost should be paid by the affiliated institution. However, please

consult individually to us in the case that your personnel costs must be paid from external funds which are acquired by yourself, as a hiring requirement of affiliated institution.